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No. 134

IN THE

Supreme Court of the United States

October Term, 1948

RESEARCH LABORATORIES, INC.,
Petitioner,

v.

UNITED STATES OF AMERICA

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

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Your petitioner, Research Laboratories, Inc., respectfully prays that a writ of certiorari issue to review the decree of the United States Circuit Court of Appeals for the Ninth Circuit, entered herein on April 2, 1948, affirming the judgments of the District Court of the United States for the Western District of Washington, Southern Division.

Opinion Below

The opinion of the Circuit Court of Appeals (R. 1102-1134) is reported in 167 F. 2d 410. The District Court wrote no opinion.

Jurisdiction

The decree of the Circuit Court of Appeals was entered on April 2, 1948 (R. 1135). On April 29, 1948, it stayed its mandate pending application to this Court for a writ of certiorari. The jurisdiction of this Court is invoked under Section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925.

Question Presented

Whether, in a libel proceeding involving an allegation of false and misleading labeling concerning the effectiveness of a drug product in violation of the Federal Food, Drug, and Cosmetic Act, it is proper to submit the case to the jury when the evidence shows that there is an honest difference of medical opinion concerning the article's effectiveness.

Statute Involved

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended, 21 U. S. C. 301 et seq.) are set out in the Appendix.

Statement

Petitioner is a corporation engaged in the manufacture, sale and distribution of a proprietary drug product known as "Nue-Ovo". Respondent filed four libel actions involving the article in three different federal district courts pursuant to Section 304(a) of the Federal Food, Drug, and Cosmetic Act (R. 2, 56, 78, 92). Each alleged that the article's labeling was "false and misleading" within the meaning of Section 502(a) of the Act (21 U. S. C. 352(a)), in that the labeling represented the article as effective in the treatment of arthritis, rheumatism, neuritis, sciatica and lumbago, whereas, it was alleged, the article is not effective in the treatment of those conditions (R. 4, 58, 80, 94). In accordance with Section 304(b) of the Act (21 U. S. C. 334

(b)), all of the cases were removed to and consolidated for trial in the District Court of the United States for the Western District of Washington, Southern Division (R. 17).

Following pre-trial conferences, the district court entered a pre-trial order (R. 20-29) stating that the agreed issues were (R. 22-23, 646-647): (1) whether the labeling suggests that the article is effective in the treatment of arthritis, rheumatism, neuritis, sciatica or lumbago; (2) whether the article is ineffective in the treatment of those conditions; and (3) whether the article is therefore misbranded. There was no issue of harmfulness in the cases (R. 23). Petitioner later admitted that the labeling represented the product to be effective (R. 1068, 1105), so that the only real issue was whether the product is effective.

At the trial before a jury, petitioner presented 27 lay witnesses[1] and 5 medical experts, all of whom testified that the product is effective. The medical testimony in support of the product may be briefly summarized as follows:[2]

(1) Dr. Ira. A. Manville, a practitioner for 23 years and Associate Professor of Medicine at Oregon State University (R. 800), testified that he had conducted clinical tests with the article from 1939 to 1942 (R. 801-802). He concluded that 65% of the patients were definitely benefited (R. 802-807, 813-823, 826-828). Also, he has used it on his own private patients with good results (R. 809).

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[1] See R. 629, 677, 680-681, 685-686, 692, 698, 703-705, 712, 715, 718-719, 724, 728, 798, 895, 899-900, 912-913, 917-918, 922, 927, 932-933, 938, 942, 946, 948-949, 953-954, 958, 962-963.

[2] A considerable part of petitioner's medical testimony related to Sal-Trag rather than Nue-Ovo. Sal-Trag is simply a concentrated form of Nue-Ovo prepared for sale to licensed physicians, whereas Nue-Ovo is sold to consumers (R. 781-783). The trial court instructed the jury that if it found the two to be the same, it should consider the Sal-Trag evidence as applicable to Nue-Ovo (R. 1065). The uncontradicted evidence was that they are identical (R. 781-783, 747-748, 786, 801). The trial court obviously was satisfied in this regard, for in the earlier stages of the trial it ruled that unless the identicalness were shown the Sal-Trag evidence would be excluded (R. 736, 777), and after introduction of the evidence above referred to it overruled respondent's objection to such evidence (R. 803). The Circuit Court of Appeals was also satisfied that the two articles are the same (R. 1103). It is apparent therefore that the testimony on both articles is entitled to the same weight.

(2) Dr. G. M. Taylor, a practitioner for 22 years, senior orthopedic doctor at Los Angeles General Hospital and acting head of the Department of Orthopedic Surgery at the College of Medical Evangelists, a grade-A medical school (R. 967-968), testified that he had conducted clinical tests with the article for a period of 3 years (R. 969-970, 974). Alternating over 100 patients, he used a vaccine treatment in general use at the time on one and the article in question on another, and found that the product was effective in from 78 to 88% of the cases, as compared with from 46 to 59% in the case of the vaccine (R. 970-973). He has also used the article in private practice with beneficial results (R. 973-974).

(3) Dr. Carl E. Lund, a practitioner for 10½ years, Vice-President of St. Joseph's Hospital in Burbank, California and on the staffs of several other hospitals (R. 993-994), testified that he had used the article on his patients for over 9 years with good results (R. 994-996). In his own practice, he used laboratory tests to determine whether the article brought any real improvement, rather than relying on the statements of patients (R. 996-997). He concluded that the article was effective in from 85 to 90% of the cases (R. 998-1004).

(4) Dr. Daniel E. Snell, a Doctor of Osteopathy in practice for 24 years (R. 776, 884), testified that he had used the product with his patients for 11 years with beneficial results in about 75% of the cases (R. 878-883). Also, he had taken the product himself with similar effectiveness (R. 874-877).

(5) Dr. Wendell White, a practicing physician for 34 years (R. 732), testified that he had used the article effectively with his patients for 8 years (R. 736, 740-742, 744-745). Likewise, he took it himself with good results (R. 738-739).

The evidence also showed that in the Los Angeles area alone approximately 1219 doctors have used the product, and 237 of them have used it consistently and in quantity for a period of from 2 to 12 years (R. 633-634).

Respondent presented 7 lay users who testified that the product had been ineffective in their cases, and 8 doctors who gave their opinions on the question of effectiveness. This medical testimony may be summarized as follows:

(1) Three doctors testified that they had made studies with the product, in the sense that they had given it to a limited group of patients over a short period of time. One gave it to six patients for 60 days and conducted laboratory tests on the patients, after which she concluded that five did not improve and one felt better (R. 351-353). Another administered the article to six patients for six weeks, made no laboratory tests, and testified that five patients felt no improvement while one did (R. 267-269). The third gave the product to seven patients for 60 days while conducting simultaneous laboratory tests on them, and reported no improvement in any of the patients (R. 399-400). All of these three doctors testified that on the basis of their limited tests it was their *opinion* that the product was not effective (R. 356-359, 272, 274, 276, 404)[3].

(2) Two doctors who had never used or prescribed the product went through the list of ingredients one by one and testified that in their *opinion* each of the ingredients would be ineffective (R. 193-202, 225-227). Both also testified that ingredients which are individually ineffective do not become effective by combination (R. 202-203, 230-231)[4].

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[3] Each of these three doctors also testified as to opinions formed on the basis of earlier tests made with a product sold under the same name but having different ingredients (R. 353, 270, 401).

[4] In contrast with this testimony, three of petitioner's medical experts testified that individually ineffective ingredients often become effective through combination (R. 771, 774, 810-811, 1012).

(3) Three doctors who have never had any experience with the product testified, simply on the basis of a reading of the article's ingredients and quantitative analysis, that in their *opinion* the product would not be effective (R. 486-488, 560-562, 579-581).

At the close of the evidence, petitioner moved for a directed verdict in each case (R. 1045-1046), and later to set aside the verdicts and judgments for respondent (R. 38), on the ground that the evidence showed only a difference of opinion between qualified physicians as to the effectiveness of the article. The motions were denied (R. 1050, 45, 75, 90, 103), and petitioner appealed to the Circuit Court of Appeals (R. 46, 76, 91, 104). The judgments of the district court were stayed pending appeal (R. 34, 70, 85, 99).

On April 2, 1948, the Circuit Court of Appeals rendered an opinion affirming the judgments of the district court (R. 1102-1134). It recognized that this Court had established in three cases [5] that there should be a directed verdict against the Government when the evidence shows an honest difference of opinion concerning the effectiveness of a product. It concluded, however, that the rule of this Court had been limited by several later lower federal court decisions. It held that respondent's expert testimony concerning tests made with the product, as to the consensus of medical opinion regarding the value of its individual ingredients, and their personal opinions even in the absence of any experience with the product, was "ample evidence to support the verdict of the jury" (R. 1117-1118). It did not mention petitioner's expert testimony and did not once discuss the question of whether the evidence as a whole showed an honest difference of opinion. Ap-

[5] *School of Magnetic Healing v. McAnnulty*, 187 U. S. 94; *United States v. Johnson*, 221 U. S. 488; *Seven Cases v. United States*, 239 U. S. 510.

parently, it reasoned that respondent's evidence was factual and not opinion evidence, that the question of effectiveness thus became one of fact, and that therefore it was a question for the jury no matter what the difference of opinion.

Specification of Errors to be Urged

The Circuit Court of Appeals erred:

(1) In holding that it was proper to submit the case to the jury even though the evidence showed that there was an honest difference of medical opinion concerning the article's effectiveness.

(2) In holding that respondent's evidence was factual, and that therefore it was proper to submit the case to the jury, despite the great amount of testimony of qualified experts that the article is effective.

(3) In affirming the judgments of the district court.

Reasons for Granting the Writ

1. The Circuit Court of Appeals has decided a federal question in a way in conflict with applicable decisions of this Court.

In *School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, this Court held that the federal statute permitting the Postmaster General to close the mails to persons engaged in obtaining money by false and fraudulent pretenses could not be construed to apply to any case in which there was a difference of medical opinion concerning the effectiveness of a particular treatment. The Court said that such an application of the statute would raise "some grave questions of constitutional law" (187 U. S. at 103).

A few years later, in *United States v. Johnson*, 221 U. S.

488, this Court came to a somewhat similar conclusion with respect to the Food and Drugs Act of June 30, 1906 (34 Stat. 768), which made it unlawful to misbrand products by means of "false or misleading" statements in the labeling. It held that the definition of misbranding contained in that Act did not apply to statements in labels concerning the effectiveness of a drug. One reason given for this conclusion was that it was considered unlikely that Congress would "distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart" (221 U. S. at 498). Mr. Justice Hughes wrote a dissent, joined in by Mr. Justice Harlan and Mr. Justice Day, concluding that the Act did apply to statements dealing with effectiveness in cases where the product was "absolutely worthless and hence the label demonstrably false" (221 U. S. at 507), but adding (*id.*):

> I entirely agree that in any case brought under the act for misbranding,—by a false or misleading statement as to curative properties of an article,—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion.

Following the *Johnson* decision, Congress by Act of August 23, 1912 (37 Stat. 416), amended the Food and Drugs Act to provide that a drug product should be deemed misbranded if its label contained any "false and fraudulent" statement concerning the article's effectiveness. In *Seven Cases v. United States,* 239 U. S. 510, this Court in an opinion written by Mr. Justice Hughes held the statute constitutional, stating that Congress had "deliberately excluded the field where there are honest differences of opinion between schools and practitioners" (239 U. S. at 517).

By the Act of June 25, 1938 (52 Stat. 1040) Congress enacted the present Federal Food, Drug, and Cosmetic Act. It provides that a drug is misbranded "if its labeling

is false or misleading in any particular" (21 U. S. C. 352 (a)). The legislative history of this Act makes it abundantly clear that Congress, following the principle announced in the above cases, intended the present statute to have no application to instances in which there is a difference of medical opinion on the issue of effectiveness.[6] Therefore, the doctrine of those cases is equally applicable to the present statute.

In the case at bar, the Circuit Court of Appeals expressly recognized that it was going beyond that doctrine. It relied on what it called "Three Limitations to the McAnnulty

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[6] H. Rept. 2139, 75th Congress, 3d Session, accompanying Bill S. 5, which became the present law, states (p. 7):

"There are clear implications in cases arising under the old Food and Drugs Act and other laws that Congress may not, by a simple and unqualified prohibition against misleading representation, penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs [citing cases].

"The reason for this limitation on the power of Congress is apparent. Whether the labeling of an article would be misleading and the product be thus misbranded would depend in a prosecution on whether the jury found it to be misleading.

"If Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute. There would therefore exist the kind of uncertainty which would invalidate the statute."

This report goes on to state that one of the important reasons for the inclusion of § 201 (n) of the Act (21 U. S. C. 321 (n)), which requires labeling "to reveal facts material in the light of" representations made, was that (p. 8):

> "If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth."

The instant case was not, of course, tried or decided below on the issue of failure to reveal the existence of conflicting medical opinion—in which respect the labeling could easily be corrected—but on the flat issue of ineffectiveness. It is clear from this legislative history that the present Act was not intended to prohibit representations as to effectiveness supported by medical opinion.

Rule" (R. 1107). It held that the "McAnnulty case [has been] carefully limited in later decisions" (R. 1110)—all, as the opinion shows, decisions of lower federal courts. Those three limitations, according to the opinion, are (a) expert testimony as to tests made with the product, (b) testimony as to the consensus of medical opinion concerning the individual ingredients of the article, and (c) expert witnesses' personal opinions regarding its effectiveness, but based on no actual experience with the article (R. 1111-1118). The Circuit Court of Appeals apparently concluded that where the Government produced testimony of any one, or all, of these three kinds the question of effectiveness became a factual one for the jury, no matter how much honest, qualified medical opinion there might be in support of the product.[7]

We submit, first, that this well settled principle of the *McAnnulty* and other cases should not be fundamentally limited without consideration by this Court and, second, that the ruling of the Circuit Court of Appeals is plainly wrong. The rule of the *McAnnulty* and related cases is that, if there is an honest difference of medical opinion, the Court must direct a verdict against the Government. There is such an honest difference of opinion where there is qualified medical opinion in favor of the product as well

[7] The Circuit Court of Appeals attempted to bolster its decision by pointing to what it called factual evidence of untruths and half-truths in the labeling, which it said were alone enough to constitute misbranding (R. 1118-1122). In this connection, it referred to two testimonial letters which respondent had tried to discredit. It also referred to statements from reference books repeated in the labeling to identify the various ingredients, and to evidence introduced by respondent that the reference books contained certain unfavorable remarks which petitioner did not include in the labeling.

But that evidence is completely irrelevant to the issues on which the case was tried, and the verdicts of misbranding could not have been based on it. The sole issues in the case were whether the labeling represented the product as effective, and whether it is effective. These were the only issues raised in the libels (R. 4, 58, 80, 94). The district

as against it. The rule adopted by the Circuit Court of Appeals is that, if the Government introduces evidence based on clinical tests, then the case should go to the jury no matter what the nature or weight of the evidence in favor of the product.

Actually, the doctrine of the instant case would completely nullify the principle established by this Court's decisions. In any case where there is a difference of medical opinion, the Government undoubtedly can secure evidence based on such clinical tests as there were in this case. Under the instant doctrine, it would make no difference that equal or even stronger evidence based on similar clinical tests was introduced in support of the product. All such cases would go to the jury to weigh the conflicting evidence.

This result is fully exemplified in the case at bar. The record shows that all of respondent's expert testimony was

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court's pre-trial order expressly stated that these were the agreed issues (R. 22-23). And in its charge to the jury, the trial court time and again reiterated that these were the sole issues (R. 1057, 1060-1062, 1064-1065, 1067-1070, 1086, 1089-1090). The jury could not have reached its verdicts, therefore, without finding that the product is ineffective; in fact, the district court expressly so charged the jury (see, particularly, R. 1090). The accuracy of the testimonials and the completeness of the statements from the reference books have absolutely nothing to do with the question of whether the product is effective. Thus this evidence could not in any way have formed the basis of the verdicts.

This was expressly recognized by both courts below in their treatment of another aspect of the case. After entry of the judgments in the trial court, petitioner moved for release of the products under bond to permit amendment of the labeling to bring it into compliance with the law (R. 41, 72, 87, 101). Obviously, if the testimonials and statements from reference books constituted the misbranding, the labeling could easily be corrected to conform to the statutory requirements, as authorized by Section 304 (d) of the Act (21 U. S. C. 334 (d)). The district court denied the request, however, on the express ground that the jury had determined that the product is ineffective (R. 1096-1097). The Circuit Court of Appeals affirmed this ruling on precisely the same ground (R. 1133-1134). This conclusively demonstrates that both courts were of the view that the jury's verdicts were based solely on the finding that the product is ineffective.

actually *opinion* evidence (see pp. 5-6, *supra*. The court below in discussing this evidence time and again referred to it as *opinion* testimony (R. 1111, 1112, 1114, 1115, 1116, 1117, 1118). Yet it concluded that, because this testimony was based on clinical tests, it somehow became "factual" and presented an issue for the jury. Much of the testimony introduced by petitioner was also based on clinical tests (see pp. 3-4, *supra*). We think it is clear from the record that petitioner's medical evidence actually was stronger and better founded than respondent's. In any event, there certainly was a great amount of qualified expert testimony in support of the product. Despite this difference of medical opinion, the Circuit Court of Appeals held it a proper case for the jury. In practical effect, this is an overruling of the decisions of this Court.

2. The decision of the Circuit Court of Appeals determines an important question under the Federal Food, Drug, and Cosmetic Act which has not been, but should be, decided by this Court.

Basically, the question here concerns the application of the misbranding provisions of the Federal Food, Drug, and Cosmetic Act of 1938 to statements in labeling concerning the effectiveness of drug products. In *United States v. Johnson*, and *Seven Cases v. United States, supra,* this Court decided similar questions concerning the construction of the Food and Drugs Act of 1906, and the amendment of August 23, 1912. The Act has since been amended in 1938 to include labeling that is "false or misleading in any particular." This Court has never had occasion to consider the application of that provision to a statement concerning effectiveness supported by qualified medical opinion.

The rule of the above cases, as we understand them, is that labeling which represents a product as effective is not "false or misleading" as a matter of law, if there is qualified medical opinion in support of that view. As stated above (p. 9, fn. 6), the Act of 1938 was not intended to change this rule. The Circuit Court of Appeals has not suggested that the Act had any such effect. Nevertheless, the court below has, we think, applied the Act in a way entirely inconsistent with the rule under the earlier statutes.

That juries should decide between schools of medicine in the field of opinion, as the court below has held, is a doctrine which should not be entertained at least in the absence of clear and explicit congressional intent. Here Congress has stated the contrary and the court below has ignored that intent. We submit that this Court should decide the question of the proper application of the present Act in such a case as this.

3. The decision of the Circuit Court of Appeals raises serious questions as to the constitutionality of the Federal Food, Drug, and Cosmetic Act which should be decided by this Court.

The three decisions of this Court discussed above indicate very clearly that a statute proscribing labeling which reflects honest medical opinion concerning a drug's effectiveness would raise serious constitutional questions. The decision of the Circuit Court of Appeals applies the Act in just that way.

This Act is enforceable by criminal penalties (21 U. S. C. 333), as well as by libel and injunction proceedings. Under the decision below, all manufacturers and distributors of drug products concerning which there is any adverse medi-

cal opinion—which undoubtedly includes a great majority of such products—will be in constant danger of losing their personal liberty or private property on the basis of a jury's weighing of conflicting medical opinions. Such an application of the Act makes it so uncertain as to amount to a deprivation of due process of law in violation of the Fifth Amendment to the Constitution. *United States v. Cohen Grocery Co.*, 255 U. S. 81; *Connally v. General Const. Co.*, 269 U. S. 385; *Winters v. New York*, 333 U. S. 507, 517. Also, such an application does not permit the laying of a definite charge as required by the Sixth Amendment. If the statute is to be applied in this way, we submit that this Court should consider these important constitutional questions.

CONCLUSION

It is respectfully submitted that this petition for a writ of certiorari to the United States Circuit Court of Appeals for the Ninth Circuit should be granted.

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July 1948

APPENDIX

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended, 21 U. S. C. 301 et seq.) are as follows:

Sec. 201. For the purposes of this Act—

• • • •

(g) The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .

• • • •

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations . . .

Sec. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

• • • •

Sec. 304 (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or

at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury . . .

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

• • • •